IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KILEY WOLFE,	:	**CIVIL ACTION**
Plaintiff,	:	
v.	:	**NO. 07-0348**
MCNEIL-PPC INC.; MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a division of MCNEIL-PPC, INC.; MCNEIL CONSUMER HEALTHCARE, a division of MCNEIL-PPC, INC; JOHNSON & JOHNSON, INC., and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC,	:	
Defendants.	:	

O R D E R

AND NOW, this 6th day of January, 2012, upon consideration of Defendants' Motion in Limine No. 1 to Exclude Evidence of or Reference to Adverse Event Reports (Document No. 158, filed August 22, 2011), Defendants' Motion in Limine No. 2 to Exclude Evidence of Adverse Drug Reaction Data Listings from the World Health Organization (Document No. 159, filed August 22, 2011), Defendants' Motion in Limine No. 3 to Exclude Evidence of Stevens-Johnson Syndrome References in the Boston University Fever Study Data (Document No. 160, filed August 22, 2011), Defendants' Motion in Limine No. 4 to Exclude Evidence That the OTC Children's Motrin Label Should Have Contained Warnings Rejected by the FDA (Document No. 161, filed August 22, 2011), Defendants' Motion in Limine No. 5 to Exclude the 2005 Citizen's Petition (Document No.

162, filed August 22, 2011), Defendants' Motion in Limine No. 6 to Exclude Evidence of McNeil's 1984 Citizen's Petition and Subsequent Petition for Reconsideration (Document No. 163, filed August 22, 2011), Defendants' Motion in Limine No. 7 to Exclude Evidence of or Reference to McNeil's Volulntary [sic] Recalls of Certain Products (Document No. 164, filed August 22, 2011), Defendants' Motion in Limine No. 8 to Exclude Evidence of or Reference to Foreign Labeling and Regulatory Actions (Document No. 165, filed August 22, 2011), Defendants' Motion in Limine No. 9 to Exclude Evidence of Inadmissible Hearsay Statements Made by FDA Employees Regarding Children's Motrin (Document No. 166, filed August 22, 2011), Defendants' Motion in Limine No. 10 to Exclude Any and All Marketing and Promotional Materials Related to Children's Motrin Not Reviewed and Relied Upon by Plaintiff or Her Family (Document No. 167, filed August 22, 2011), Defendants' Motion in Limine No. 11 to Exclude Evidence of Other Lawsuits, Claims, or Settlements Involving Children's Motrin or Other Ibuprofen Products (Document No. 168, filed August 22, 2011), Defendants' Motion in Limine No. 12 to Exclude Testimony or Questions Regarding Rechallenges Occurring in Upjohn Clinical Trials (Document No. 169, filed August 22, 2011), Defendants' Motion in Limine No. 13 to Exclude Evidence of or Reference to Drugs Withdrawn or Removed from the Market (Document No. 170, filed August 22, 2011), Plaintiff's Motion in Limine to Exclude Any Evidence, Reference, Argument, Suggestion and/or Innuendo That Anyone Other Than a Drug Manufacturer Has the Ultimate Responsibility for Providing Adequate Warning Labels (Document No. 174, filed August 22, 2011), Plaintiff's Motion in Limine to Exclude Any Evidence, Reference, Argument, Suggestion and/or Innuendo That Compliance with FDA Regulations Absolve [sic] Defendants of Liability as a Matter of Law (Document No. 175, filed August 22, 2011), Plaintiff's Motion in Limine to Exclude Any Evidence, Reference, Argument, Suggestion and/or Innuendo That a Drug Manufacturer Could Not Change the Warning

Label on Medication Without Prior FDA Approval (Document No. 176, filed August 22, 2011), Plaintiff's Motion in Limine to Exclude Any Evidence or Reference to the Current FDA Preamble (Document No. 177, filed August 22, 2011), Plaintiff's Motion in Limine to Exclude Any Evidence, Reference, Argument, Suggestion and/or Innuendo That Plaintiff's Mother Uses Ibuprofen or Gives It to Her Other Children (Document No. 178, filed August 22, 2011), Plaintiff's Motion in Limine to Preclude Defendant Johnson & Johnson from Denying That It Manufactures, Markets, Distributes and Sells Children's Motrin (Document No. 179, filed August 22, 2011), Plaintiff's Motion in Limine to Exclude Any Evidence, Reference, Argument, Suggestion and/or Innuendo That Kiley Wolfe Did Not Have Stevens-Johnson Syndrome (Document No. 180, filed August 22, 2011), Plaintiff's Motion in Limine to Exclude Any Evidence, Reference or Testimony That Kiley Wolfe Took Aleve (Document No. 185, filed August 22, 2011), and the related submissions of the parties, for the reasons set forth in the Memorandum dated January 6, 2012, **IT IS ORDERED** as follows:

1. Defendants' Motion in Limine No. 1 to Exclude Evidence of or Reference to Adverse Event Reports is **GRANTED WITHOUT PREJUDICE** to plaintiff's right to seek reconsideration at trial with respect to particular Adverse Event Reports ("AERs"). AERs that (1) concern Stevens-Johnson Syndrome ("SJS") and related illnesses associated with the use of ibuprofen and (2) were submitted to the FDA before plaintiff became ill may be admissible on the issue of defendants' notice of potential safety risks from the use of Children's Motrin. With the possible exception of AERs that were sent to the FDA by defendants, AERs are not admissible for the truth of the matter asserted. The Court defers ruling on the admissibility of any particular AER, as the parties submitted only two examples to the Court. Expert testimony that relies, in part, on AERs is admissible, but the proponent of the opinion may not disclose such AERs to the jury unless the Court determines that the AERs' probative value in assisting the jury to evaluate the expert's

opinion substantially outweighs their prejudicial effect;

2. Defendants' Motion in Limine No. 2 to Exclude Evidence of Adverse Drug Reaction Data Listings from the World Health Organization is **GRANTED WITHOUT PREJUDICE** to plaintiff's right to seek reconsideration at trial with respect to particular World Health Organization ("WHO") data listings. WHO data listings that (1) concern SJS and related illnesses associated with the use of ibuprofen and (2) pre-date plaintiff's illness may be admissible, subject to their authentication at trial, on the issue of defendants' notice of potential safety risks from the use of Children's Motrin. With the possible exception of data listings that were sent to the WHO by defendants, WHO data listings are not admissible for the truth of the matter asserted. The Court defers ruling on the admissibility of any particular WHO data listing, as the parties submitted none to the Court. Expert testimony that relies, in part, on WHO data listings is admissible, but the proponent of the opinion may not disclose those data listings to the jury unless the Court determines that their probative value in assisting the jury to evaluate the expert's opinion substantially outweighs their prejudicial effect. If plaintiff fails to authenticate the WHO data listings at trial, they are not admissible for any purpose, subject to the provisions of Federal Rule of Evidence 703;

3. Defendants' Motion in Limine No. 3 to Exclude Evidence of Stevens-Johnson Syndrome References in the Boston University Fever Study Data is **GRANTED IN PART AND DENIED IN PART WITHOUT PREJUDICE** to the parties' right to seek reconsideration at trial if warranted by changed circumstances, or to object to inadmissible questions. The evidence would not be inadmissible hearsay if offered on the issue of defendants' knowledge of the risks of Children's Motrin and/or alleged misrepresentation to the FDA in failing to report two SJS cases;

4. Defendants' Motion in Limine No. 4 to Exclude Evidence that the OTC Children's Motrin Label Should Have Contained Warnings Rejected by the FDA is **DENIED**;

5. Defendants' Motion in Limine No. 5 to Exclude the 2005 Citizen's Petition is **GRANTED**;

6. Defendants' Motion in Limine No. 6 to Exclude Evidence of McNeil's 1984 Citizen's Petition and Subsequent Petition for Reconsideration is **DENIED**;

7. Defendants' Motion in Limine No. 7 to Exclude Evidence of or Reference to McNeil's Volulntary [sic] Recalls of Certain Products is **GRANTED**;

8. Defendants' Motion in Limine No. 8 to Exclude Evidence of or Reference to Foreign Labeling and Regulatory Actions is **GRANTED WITHOUT PREJUDICE** to plaintiff's right to seek reconsideration based on evidence adduced at trial and developments after the issuance of this Memorandum and Order;

9. Defendants' Motion in Limine No. 9 to Exclude Evidence of Inadmissible Hearsay Statements Made by FDA Employees Regarding Children's Motrin is **GRANTED WITHOUT PREJUDICE** to plaintiff's right to seek reconsideration based on evidence adduced at trial and developments after the issuance of this Memorandum and Order;

10. Defendants' Motion in Limine No. 10 to Exclude Any and All Marketing and Promotional Materials Related to Children's Motrin Not Reviewed and Relied upon by Plaintiff or Her Family is **GRANTED WITHOUT PREJUDICE** to plaintiff's right to seek reconsideration based on evidence adduced at trial and developments after the issuance of this Memorandum and Order;

11. Defendants' Motion in Limine No. 11 to Exclude Evidence of Other Lawsuits, Claims, or Settlements Involving Children's Motrin or Other Ibuprofen Products is **GRANTED WITHOUT PREJUDICE** to plaintiff's right to seek reconsideration based on evidence adduced at

trial and developments after the issuance of this Memorandum and Order;

12. Defendants' Motion in Limine No. 12 to Exclude Testimony or Questions Regarding Rechallenges Occurring in Upjohn Clinical Trials is **GRANTED WITHOUT PREJUDICE** to plaintiff's right to seek reconsideration based on evidence adduced at trial and developments after the issuance of this Memorandum and Order;

13. Defendants' Motion in Limine No. 13 to Exclude Evidence of or Reference to Drugs Withdrawn or Removed from the Market is **GRANTED WITHOUT PREJUDICE** to plaintiff's right to seek reconsideration based on evidence adduced at trial and developments after the issuance of this Memorandum and Order;

14. Plaintiff's Motion in Limine to Exclude Any Evidence, Reference, Argument, Suggestion and/or Innuendo that Anyone Other than a Drug Manufacturer Has the Ultimate Responsibility for Providing Adequate Warning Labels is **GRANTED**;

15. Plaintiff's Motion in Limine to Exclude Any Evidence, Reference, Argument, Suggestion and/or Innuendo that Compliance with FDA Regulations Absolve [sic] Defendants of Liability as a Matter of Law is **GRANTED**;

16. Plaintiff's Motion in Limine to Exclude Any Evidence, Reference, Argument, Suggestion and/or Innuendo that a Drug Manufacturer Could Not Change the Warning Label on Medication Without Prior FDA Approval is **GRANTED**;

17. Plaintiff's Motion in Limine to Exclude Any Evidence or Reference to the Current FDA Preamble is **GRANTED**;

18. Plaintiff's Motion in Limine to Exclude Any Evidence, Reference, Argument, Suggestion and/or Innuendo that Plaintiff's Mother Uses Ibuprofen or Gives It to Her Other

Children is **DENIED**;

19. Plaintiff's Motion in Limine to Preclude Defendant Johnson & Johnson from Denying that It Manufactures, Markets, Distributes and Sells Children's Motrin is **DENIED**;

20. Plaintiff's Motion in Limine to Exclude Any Evidence, Reference, Argument, Suggestion and/or Innuendo that Kiley Wolfe Did Not Have Stevens-Johnson Syndrome is **DENIED**; and,

21. Plaintiff's Motion in Limine to Exclude Any Evidence, Reference or Testimony that Kiley Wolfe Took Aleve is **DENIED**.

IT IS FURTHER ORDERED that, with respect to all rulings, including those in which the Court specifically stated that an aggrieved party would be permitted to seek reconsideration at trial if warranted by changed circumstances or evidence adduced at trial, any aggrieved party may seek reconsideration of the rulings in this Order.

BY THE COURT:

/s/ Hon. Jan E. DuBois
JAN E. DUBOIS, J.